

part, a method comprising identifying a subject in need of endoscopic surgery, delivering a fluid to the subject and replacing a first applicator section with a second applicator section during surgery. These amendments are supported throughout the specification, for example, on page 5, lines 12-18. claims 16 has been rewritten in independent form. The dependencies of claims 20-23, 27-41 and 34 have been changed. No new matter has been added. As a result claims 1 and 3-57 are pending.

Drawings

The drawings were objected to under 37 C.F.R. 1.83(a) for not showing the limitations in claims 6, 9-13, 47- 55. This objection is respectfully traversed.

Applicants believe that a detailed illustration of the features noted above by the Examiner are not essential for a proper understanding of the invention, and need not be illustrated in the drawing. The claims are fully supported by 35 U.S.C. 112. Withdrawal of this objection is respectfully requested.

Objection Under 37 C.F.R. 1.75(c)

Claims 20-45 were objected to under 37 C.F.R. 1.75 (c) as being improper form. Withdrawal of this objection is respectfully requested.

Claims 20-23, 27-31 and 34 have been amended to depend from a single claim. Accordingly, claims 24-26 depend from properly amended claim 23. Applicant disagrees with the Examiner's assertion that claims 35-45 are in improper form as claims 35 depends from claims 17 or 18. Therefore, claims 36-45 are in proper dependent form. Withdrawal of this objection is respectfully requested.

Rejection under 35 U.S.C. §112

Claims 2, 3, 9-11, 16 and 48 were rejected under 35 U.S.C. §112, second paragraph. This rejection is respectfully traversed.

As noted above, claim 2 has been cancelled without prejudice. As amended, claims 3 and 16 recite, in part, the steps of identifying a subject in need of endoscopic surgery and delivering a fluid to the subject.

The applicants disagree with the Examiner's assertion that "a fluid which forms at least one structure at the applicant site" recited in claim 9 is unclear. It is believed that the language, itself, is clear. Moreover, the specification describes exemplary structures at least at page 13, lines 4-14, including, without limitation, sealants, adhesives, pavings, coating, barriers, drug delivery depots, and tissue engineering matrices.

The applicants also disagree with the Examiner's assertion that the limitation "a therapeutic agent" lacks antecedent basis. As noted in the present application at page 13, lines, 15-30, one or more materials including therapeutic agents may be applied. It is understood that the same of different therapeutic agents may be applied sequentially.

Accordingly, withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. §102

Claims 1-3, 5-8, 16-19, 46 and 49-57 were rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,766,157 to Tilton, Jr. (hereinafter Tilton). This rejection is respectfully traversed.

Tilton fails to disclose, teach, or suggest a surgical device comprising two or more modular units, at least one of which is capable of being interchanged during surgery or units that are removably attachable to each other during a surgical procedure as recited, or in part, in amended claims 1, 16, and 17, or a method for conducting endoscopic surgery comprising replacing a first applicator section with a second applicator section during surgery as recited, in part, in amended claim 3. Tilton discloses a variety of dispensing members with various heads that appear to be supplied, together, as a unit. Tilton is silent on attaching heads 115-122 to flexible plastic dispensing tubes 114, but apparently provides the heads already attached to the tubes. While "selection" of various arrangements is disclosed, it is not seen how units are interchanged, *much less* interchanged during surgery.

Dependent claims are further removed from Tilton. While the applicants need not discuss each and every dependent claim that stands rejected, as they necessarily include the

limitation of the claims from which they depend (and the applicants reserve their right to address other dependent these claims in the future), it is noted that Tilton appears not to disclose or suggest a third unit capable of being added to the device or interchanged with at least one of the device during the surgical procedure as recited, in part, in claims 46) or an articulated joint as recited, in part, in claims 5 and 18 (Tilton discloses a pinned joint 37 to move relative to the longitudinal axis at column 5, lines 56-65; articulation is defined in the present application as the relationship between the axis of a first component relative to a second component, wherein the axis of the first can move in three dimensions relative to the axis of the second, for example, as allowed by a ball-and-socket joint; page 6, lines 9-18, or a snap-fit ball and socket joint and a socket connection as recited, in part, in claims 6 and 7.

The applicants also fail to observe, in Tilton, a surgical device including at least one joint at a portion of the device constructed to be passed through the cannula as recited, in part, in claim 49. Tilton discloses a joint in a main body through which a flexible dispensing tube member is passed, but is silent as to a surgical device including at least one joint at a portion of the device constructed to be passed through a cannula as recited, in part, in claim 49. Apparently the pivotal joint of Tilton does not pass through cannula.

The applicants also do not observe in Tilton a joint that facilitates rotational movement, wherein the rotational movement may be at least 90, 180 and 360, as recited in claims 50, 53-55, respectively.

As such, these claims are novel over Tilton. Claim 2 has been cancelled without prejudice. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1, 3-4 and 9-11 were rejected under 35 U.S.C. §102(e) over U.S. Patent No. 6,146,373 to Cragg et al. (hereinafter Cragg). This rejection is respectfully traversed.

Cragg fails to disclose an applicator section for delivering a fluid as recited in claim 1 and 3. The applicants disagree with the Examiner's assertion that distal end cap 46 of Cragg is an applicator section as used in the present invention. An applicator section, as used in the present invention, is a section from which a fluid exits the device for controlled application to the body. (Present application, page 7, lines 21-28.) The applicants believe that the end cap of Cragg merely supports the catheter but does not deliver a fluid. As such, claims 1 and 3 are novel over

Cragg. Claims 4 and 9-11 depend directly or indirectly from claim 3 and are novel over Cragg for at least the above mentioned reason. Withdrawal of this rejection is respectfully requested.

Claims 1 and 15 were rejected under 35 U.S.C. §102(e) over U.S. Patent No. 6,248,092 to Miraki et al. (hereinafter Miraki). This rejection is respectfully traversed.

Miraki fails to disclose a surgical device comprising two or more modular units at least one of which is capable of being interchanged during surgery, or a device that is suitable for delivery of at least one fluid during surgery as recited in amended claim 1. Miraki discloses a balloon catheter having a reusable proximal body. Nowhere do the applicants observe in Miraki interchanging a unit during surgery, or an applicator section capable of delivering at least one fluid during surgery. As such, claim 1 is novel over Miraki. Claim 15 depends from claim 1 and is novel over Miraki for at least the above mentioned reasons. Withdrawal of this rejection is, therefore, respectfully requested.

Claims 1, 12-13 and 47-48 were rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,587,072 to Lampropoulos et al. (hereinafter Lampropoulos). This rejection is respectfully traversed.

Nowhere in Lampropoulos do the applicants observe a device comprising two or more modular units at least one of which is capable of being interchanged during surgery as recited in amended claim 1. Lampropoulos discloses a catheter apparatus for delivery of a fluid but fails to disclose, teach, or suggest a unit capable of being interchanged during surgery.

Nowhere in Lampropoulos do the applicants observe a method comprising, in part, delivering a therapeutic agent via a first device, altering the first device to form a second device, and delivering a therapeutic agent via the second device as recited in claims 47 and 48. Lampropoulos is apparently silent as to altering to the catheter apparatus in between delivering a therapeutic agent. Accordingly, claims 1 and 47-48 are novel over this reference. Claims 12-13 depend directly from claim 1 and are novel over Lampropoulos for at least the above mentioned reason. Withdrawal of this rejection is respectfully requested.

Serial No.: 09/744,698
Confirmation No.: 3328

- 8 -

Art Unit: 3763

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the applicants' attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, the applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
John M. Kirwan et al., Applicants

By: 

Lisa E. Winsor, Reg. No. 44,405
Timothy J. Oyer, Ph.D., Reg. No. 36,628
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2211
Telephone: (617) 720-3500

Docket No. F00397.70050.US
Date: March 11, 2003
x03/12/03

Marked-Up Claims

1. (Amended) A surgical device comprising two or more modular units, at least one of which is capable of being interchanged during surgery, including at least a cannula section and an applicator section, wherein the device is suitable for delivery of at least one fluid during surgery and is capable of being provided in a sterilized condition.

3. (Amended) A method for conducting endoscopic surgery, the method comprising identifying a subject in need of endoscopic surgery and delivering a fluid to the subject by the use of a surgical device, wherein the device is assembled from two or more modular units including at least a cannula section and [an] a first applicator section [, wherein the device] and is suitable for delivery of at least one fluid during surgery and [is] capable of being provided in a sterilized condition, the method comprising replacing the first applicator section with a second applicator section during surgery.

16. (Amended) A kit for performing a surgical procedure, comprising [a device according to claim 1] :

a surgical device comprising two or more modular units, at least one of which is capable of being interchanged during surgery, including at least a cannula section and an applicator section, wherein the device is suitable for delivery of at least one fluid during surgery and is capable of being provided in a sterilized condition, in combination with at least one of a propulsion means for fluid, a fluid to be dispensed, and a container for the fluid.

17. (Amended) A kit for performing a surgical procedure comprising a sterilizable device with two or more units removably attachable to each other during a surgical procedure, wherein the device is constructed and arranged for passage through a cannula and capable of delivering a therapeutic agent for application to a treatment site internally of a patient.

20. (Amended) A kit according to [any of] claims [17-19] 17 or 18, wherein the two or more units are removably attachable to each other at a location that passes through a cannula during use.

21. (Amended) A kit according to [any of claim 17-20] claim 20, wherein the two or more units are removably attachable to each other at a location that passes through a cannula into a surgical treatment area during use.

22. (Amended) The kit according to [any of claims 17-21] claim 21, where the two or more units removably attachable to each other include at least a cannula section and at least an applicator section.

23. (Amended) The kit according to [any of claims 17-22] claim 22, wherein at least one of the units is removably attachable to another of the units at an articulated joint.

27. (Amended) The kit according to [any of claims 17-26] claims 17 or 18, wherein at least one of the units removably attachable to each other comprises a snap-fit ball and socket joint.

28. (Amended) The kit according to [any of claims 17-27] claim 27, wherein at least one of the units removably attachable to each other comprises at least one joint having both a taper fit connection and a snap-fit ball and socket connection.

29. (Amended) The kit according to [any of claims 17-28] claims 17 or 18, wherein at least one of the units removably attachable to each other comprises at least one of a valve limiting orifice.

30. (Amended) The kit according to [any of claims 17-29] claims 17 or 18, wherein at least one of the units removably attachable to each other further comprises a molded part.

Serial No.: 09/744,698
Confirmation No.: 3328

- 11 -

Art Unit: 3763

31. (Amended) The kit according to [any of claims 17-30] claims 17 or 18, wherein at least one of the units removably attachable to each other has the attribute of at least one of radio-opacity; color-coding; controlled flexibility; lack of magnetic responsiveness; intraoperative removability; and passability therethrough of optical fibers or sensors.

34. (Amended) The kit according to [claims 32 or] claim 33, wherein the applicator is a brush.